भारतीय मानक
Indian Standard

IS 17533 : 2021

पैराफ़ीन वितरक — विशिष्टि

Paraffin Dispenser — Specification

ICS 11.140

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भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुरशाह ज़फर मार्ग, नई दिल्ली – 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI-110002
www.bis.gov.in www.standardsbis.in

April 2021 **Price Group 2**

Anatomy and Forensic Sciences Equipment Sectional Committee, MHD 23

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the draft finalized by the Anatomy and Forensic Sciences Equipment Sectional Committee and approved by the Medical Equipment and Hospital Planning Division Council.

This standard describes the specifications for Paraffin dispenser used in Histopathology, Forensic Medicine and Anatomy Lab, where wax embedded moulds or blocks are prepared. The Paraffin wax dispenser is designed to melt bulk quantities of pelletised wax.

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this standard.

Indian Standard

PARAFFIN DISPENSER — SPECIFICATION

1 SCOPE

This Indian Standard specifies basic requirements for Paraffin dispenser used in Histopathology, Forensic Medicine and Anatomy Lab, where wax embedded moulds or blocks are prepared. These dispensers are specially designed for use where large volume of paraffin is required, to facilitate disposing of wax for embedding purpose.

2 REFERENCE

The standards listed below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below.

IS No./Other Publication	*Title*
IS 4654 : 1993	Paraffin Wax — Specification (*second Revision*)
IS/IEC 61010-1 : 2010	Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements
IS/ISO 14971 : 2019	Medical devices — Application of risk management to medical devices (*under print*)
IS/IEC 61010-2-101 : 2018	Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment (under print)

3 TERMS AND DEFINITIONS

3.1 Paraffin Dispenser — A Paraffin or Wax dispenser melts the solid paraffin, maintains it in its molten form and dispenses it as and when required. The dispenser is separately heated to maintain the same temperature as the paraffin reservoir.

4 REQUIREMENTS

4.1 General Requirements

The equipment shall comply with the Requirements of **IS/IEC 61010-1** and **IS/IEC 61010-2-101**.

4.2 Safety Requirements

The device should comply with all safety requirements as described in **IS/IEC 61010-1**.

4.3 Quality control and Risk Management

The device shall comply to **IS/ISO 14971**.

5 DESIGN

5.1 Material and Construction

5.1.1 The outer chamber of the dispenser shall be made up of Stainless steel sheet of minimum 0.8 mm thickness. The construction of the dispenser shall be either seamless or with seams welded, soldered, brazed, double seamed or swaged with smooth finish without any sharp edges or welding defects.

5.1.2 The capacity of the tank shall be up to 7.5 litres, smaller sizes e.g. 5 litres, 3.5 litres, 2.5 litres can be made as per the customer requirements.

5.1.3 The inner tank shall have a filter screen (approx. 0.5 mm mesh) fitted to prevent coarse particles from blocking the delivery tap. The tank shall be fully insulated to prevent heat loss from the tank and ensure the outer surfaces of the tank are safe to touch. Temperature of outside surface shall not exceed 40 °C at any point except dispensing point.

5.1.4 Lid for covering the dispenser shall be made of Stainless Steel or plastic with adequate strength and thickness.

5.1.5 A knob made up of plastic shall be provided to facilitate lifting of the Lid without being overheated

5.2 Temperature Control

5.2.1 Temperature is controlled by thermostat and is kept at approx 65 °C. Inner chamber made of joint-less deep drawn Stainless Steel for better temperature uniformity and outer part is either power coated or mild steel sheet dully insulated for ease to operate.

5.2.2 In case of Paraffin Dispenser with Digital controls, temperature is controlled by digital temperature controller cum indicator with provision to set temperature values by the user. The 'current' and 'set' temperature values shall be displayed on the LED screen.

5.3 Melting Time

The Melting time of entire wax should be maximum one hour when tested as per Annex A.

5.4 Melting Point

The determination of melting point shall comply with A 1.1 of Annex A of IS 4654.

5.5 Environment Conditions

The working area shall be stable, clean, dry and ventilated with relative humidity of ≤ 80 %.

5.6 Power supply

The power supply connection of the equipment shall be suitable for 230 Volts, 1 phase, AC supply.

6 OPERATING PARAMETERS

6.1 To ensure an even flow of wax, the wax dispenser tap shall have a dedicated heating system with three settings – off, on-demand pull dispense and continuous flow to prevent solidification and blockage.

7 OPERATING MANUAL

Each device shall be accompanied by an operating manual which shall contain the following information:

a) Instructions and plan for installation,
b) Operation of the apparatus, and
c) Routine maintenance and service.

8 MARKING AND PACKING

8.1 The device shall be legibly and indelibly marked at a suitable place with

a) Unique device identification number;
b) the manufacturer's name,
c) initials or recognized trade-mark;
d) serial number;
e) the country of manufacture.

8.2 The device may be packed as agreed to between the purchaser and the supplier.

8.3 The device shall be securely packed, in any manner, acceptable to the purchaser, so as to minimize the risk of damage in handling, transport and storage.

9 BIS CERTIFICATION MARKING

9.1 The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

ANNEX A

(*Clause* 5.3)

MELTING TIME

A-1.0 Testing Procedure

A-1.1 The paraffin dispenser shall be filled with pelleted wax as per manufacturer's recommendation according to its capacity.

A-1.2 Heater shall be switched 'on' and time shall be noted with taps closed and lid duly covered.

A-1.3 After one hour, the molten paraffin shall be collected in a measuring jar till the entire paraffin wax flows out. The quantity collected should be within ± 2 % of initial quantity loaded.

ANNEX B

(*Foreword*)

COMMITTEE COMPOSITION

Anatomy and Forensic Sciences Equipment Sectional Committee, MHD 23

Organization	*Representative(s)*
Maulana Azad Medical College, New Delhi	Dr Sabita Mishra (***Chairperson***)
AIMED (Delhi)	Shri Rajesh Khatri Mrs Lalita Khatri (*Alternate*)
Dept of Forensic Medicine, Sri Ramachandra Medical College & Research Institute, Chennai	Dr P. Sampath Kumar Dr Venicatesan M. (*Alternate* I) Dr Sneha S. (*Alternate* II)
Directorate General of Health	Dr Anita Tuli Dr M. K. Wahi (*Alternate*)
Federation of Indian Chambers of Commerce and Industry (FICCI), New Delhi	Shri Vijay Kumar Dr Sandeep Sewlikar (*Alternate*)
Indian Medical Association, Delhi	Dr R. V. Asokan Dr N. V. Kamat (*Alternate*)
Kalam Institute of Health Technology, Visakhapatnam	Shri Kingshuk Poddar Shri P. Srinivasa Reddy (*Alternate* I) Shri Dilip Kumar Chekuri (*Alternate* II)
LNJN National Institute of Criminology and Forensic Science, Delhi	Dr K. P. S. Kushwaha Dr J. K. Modi (*Alternate* I) Dr Tanya Chauhan (*Alternate* II)
Maulana Azad Medical College, New Delhi	Dr Dinesh Kumar Dr Srinivas M. (*Alternate* I) Dr Swati Tiwari (*Alternate* II)
National Health Systems Resource Centre, New Delhi	Shri Ajai Basil Shri Bharat Bhushan Dahiya
North Delhi Municipal Corporation Medical College, Hindu Rao Hospital, Delhi	Dr (Prof) Saudan Singh Dr Gayatri Rath (*Alternate* I) Dr Neha Gupta (*Alternate* II)
Sri Ramachandra Institute of Higher Education and Research, Chennai	Dr (Lt Col) T. Vijaya Sagar Dr S. Senthil Kumar (*Alternate* I) Dr Venkatesan M. (*Alternate* II)
VMMC & Safdarjung Hospital, New Delhi	Shri Manoj Kumar Wahi Shri G. A. Sunil Kumar Sharma (*Alternate* I) Shri Manish Kumath (*Alternate* II)
BIS Directorate General	Shri Prakash Bachani Scientist 'F' and Head (MHD) [Representing Director General (*Ex-officio*)]

Member Secretary

Dr Pradeep Dua
Scientist 'C' (MHD), BIS

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BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:		*Telephones*
Central	Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	2323 7617 2323 3841
Eastern	1/14 C.I.T. Scheme VII M, V.I.P. Road, Kankurgachi KOLKATA 700054	2337 8499, 2337 8561 2337 8626, 2337 9120
Northern	Plot No. 4-A, Sector 27-B, Madhya Marg CHANDIGARH 160019	265 0206 265 0290
Southern	C.I.T. Campus, IV Cross Road, CHENNAI 600113	2254 1216, 2254 1442 2254 2519, 2254 2315
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